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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,203	03/25/2005	Horst Bauer	268034US0PCT	4774

22850 7590 04/20/2007

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EXAMINER	
HA, JULIE	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
31 DAYS	04/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 04/20/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/529,203	BAUER ET AL.	
	Examiner	Art Unit	
	Julie Ha	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-60 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-47 and 55-60, drawn to a pharmaceutical gel preparation, a method for producing a pharmaceutical preparation and a kit for producing a pharmaceutical preparation and a method for treating a patient with a pharmaceutically active peptide compound.

Group II, claim(s) 48-53, drawn to a method for treating a hormone-dependent disorder in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation.

Group III, claim(s) 54, drawn to a method for modifying the reproductive function in a patient by subcutaneous or intramuscular administration of a pharmaceutical preparation.

A national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) a product and a process specially adapted for the manufacture of said product; or

(2) a product and a process of use of said product; or

(3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) a process and a apparatus specifically designed for carrying out said process; or

(5) a product, a process specially adapted for the manufacture of the said product and an apparatus specifically designed for carrying out said process. 37 CFR 1.475.

Group I, having a first product and a first method for making said product fall within category (3). PCT Rule 13 does not provide for multiple compositions or multiple methods of use within a single application. Thus, the first appearing composition is combined with a corresponding first method of making and the additional composition and method claims each constitute a separate group.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of method for treating a hormone-dependent disorder in a patient by administering to the patient in need a pharmaceutical gel preparation comprising at least one pharmaceutically active ionic peptide compound is taught by Bauer et al (PG Pub 2002/0039996). Bauer et al teach gelanic forms for the parenteral administration of peptides prone to aggregation, in particular of LHRH analogues or LHRH antagonists and agonists (see paragraph [0001]). The reference further teaches that the are of use of the preparations according to the invention is in the prevention and therapy of all sex hormone-dependent conditions and diseases which can be influenced by LHRH analogues, i.e., LHRH agonists and antagonists (see paragraph [0020]). In view of Bauer et al, the technical feature recited in Group II (see claim 48) is not special. Accordingly, the groups are not so linked as to form a single general concept under PCT Rule 13.1.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their

recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Different ionic peptide compound: cationic, anionic, mono- di- or multivalent cationic or anionic or amypholytic, centrorelix, teverelix, abarelix, azaline B, antide, detirelix, ramorelix, degarelix, D-63153;

GnRH: analog or antagonist. For GnRH analogs or antagonists, Applicant should elect a single species within the genus of GnRH analog or GnRH antagonists;

Aqueous inorganic salt or acetic salt: sodium chloride, calcium chloride, magnesium chloride, sodium acetate, calcium acetate, magnesium acetate;

Hormone-dependent disorder: prostate cancer, breast cancer, uterine myomas, endometriosis, or precocious puberty.

7. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

8. If Group I, II or III is elected, the Applicants are requested to elect a single disclosed species from ionic peptide compound, whether or not it is a GnRH analog or antagonist, an aqueous inorganic slat or acetic salt. For example, if Group I is elected, the Applicants should elect, for example D-63153, which is a GnRH antagonist, and sodium chloride, which is an inorganic salt. If Group II is elected, the Applicants are additionally requested to elect a single disclosed species of hormone-dependent disorder, such as for treating precocious puberty. If Group III is elected, the Applicants are requested to elect a single disclosed species of reproductive function (the Examiner could not find any disclosure in the specification). Again, by election of species, this means that Applicants should elect a single disclosed compound. Election of "GnRH analog" or "LhRH antagonist" is not species, but an election to a genus. An election of this nature will not be fully responsive to the election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. The claims are deemed to correspond to the species listed above in the following manner:

Claims 2-5, 8-10, 12-13, 23-26, 48-53 and 55.

The following claim(s) are generic: None.

11. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The ionic peptide compounds are different due to different amino acid compositions, and thus, having different structures. Further, search for one would not necessarily lead to the other. GnRH analog contains the class of agonist, antagonist and other analogs that function very differently from each other. For example, agonist reacts with the receptor to modulate a function of the cell. Further, search for one would not necessarily lead to the other. An antagonist, binds to a receptor, however, it inhibits the function of the cell. Further, search for one would not necessarily lead to the other. Inorganic and acetic salts are patentably independent and distinct from each other due to their structures. Further, search for one would not necessarily lead to the other. The hormone-dependent disorders are patentably independent or distinct due to their symptoms and body parts they target. Further, search for one would not necessarily lead to the other.

12. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

13. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

14. **Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.**

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Julie Ha
Patent Examiner
AU 1654

4/16/07
ANISH GUPTA
PRIMARY EXAMINER